K960538

V. 510(k) Summary

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A. Submitted By: W.L. Gore & Associates, Inc.
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B. Device Name: PRECLUDE™ IMA Sleeve

C. Applicant Device Description:

Biocompatible, expanded polytetrafluoroethylene (ePTFE) in sleeve configuration. The sleeve configuration allows a surgeon to use the device as is without the need to form and shape the device during surgical procedures. The sleeve has a nominal 17-24 mm internal diameter and a length of 10-20 cm.

D. Intended Use and Indications

A surgical membrane indicated for use as a cover and physical barrier of pedicled arterial conduits which are used as coronary artery bypass grafts. The device identifies and protects pedicled arterial conduits during reoperative cardiac surgery.

E. Predicate Device:

The surgical membrane, PRECLUDE™ Pericardial Membrane, is cited as a predicate device which has been found to be substantially equivalent through the premarket notification process.

F. Technological Characteristics:

The applicant device has the same intended use and the same indications as the predicate device.

The applicant device is manufactured using the same inert, biocompatible ePTFE material as the predicate device. Mechanical strength test results show the applicant device to have material characteristics which are substantially equivalent to the predicate device.

	Applicant	Predicate
Mean Suture Pull-Out Force	0.67 kg	0.93 kg
Mean Peak Load	9.56 kg	4.49 kg

Data from animal studies show the applicant device to exhibit no histopathological complications and to have tissue attachment characteristics consistent with the predicate device.

G. Safety and Effectiveness Conclusions:

The applicant PRECLUDE™ IMA Sleeve is equivalent in materials and manufacturing processes to the predicate PRECLUDE™ Pericardial Membrane. The applicant device is composed of the same inert, biocompatible expanded PTFE as the predicate device. As demonstrated in animal studies, tissue attachment characteristics and the histological reactions and effects of the applicant device are equivalent to those of the predicate device. Mechanical testing data reveal the applicant device has strength values which are substantially equivalent to the predicate device. The applicant device is subjected to essentially the same quality tests and quality criteria as is the predicate device. The packaging processes and materials used for the applicant device will not differ from those used for the predicate device. The applicant device will be sterilized using the same sterilization methods, utilize the same post-sterilization release criteria and have the same Sterility Assurance Level of $\leq 10^{-6}$ as the predicate device.

The sleeve feature of the applicant device does not affect the safety or effectiveness of the product. No new types of safety and effectiveness questions are raised by the applicant device when compared to the predicate device.